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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,799	TAKEDA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5 and 7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 and 6* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I (claims 1-4 and 6 as the claims read on SEQ ID NO:1) in Paper No. 12 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to search all sequences set out in the claims in one application. This is not convincing although applicants have claimed the individual antibodies directed to many different peptides as a single kit, the search for each antibody component requires a separate search of the prior art. Applicants have not provided any evidence that the search for a single sequence will necessarily provide information regarding all sequences. Applicants can provide a sequence alignment among the sequences to establish that the sequences share a common corresponding technical feature over the prior art by establishing that the sequences have common structure.

The requirement is still deemed proper and is therefore made FINAL.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3 and 6, is attached to the instant Office Action.

Drawings

The drawings are have been approved by the Draftsperson.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims make reference to "partial peptides thereof", it is not clear from the claim construction which partial peptides are intended. Does "partial peptides thereof" encompass the common structural elements with other viruses or those that do not share common structure with other viruses. Also do the partial peptides only have to have 80% sequence similarity? In order to distinguish the instant antibodies from those antibodies disclosed in the prior art the "partial peptides thereof" must be more clearly defined. The smallest peptide that can consistently elicit antibodies that recognize the original protein is 6 amino acids in length. Therefore, any polyclonal antibody that is directed at a protein that has minimally 6 amino acids in common with SEQ ID NO1 would fall within the scope of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The claims are drawn to an antibody against an isolated polypeptide having at least 80% sequence identity to the polypeptide encoding SEQ ID NO: 1 and "partial peptides thereof". The claims do not require that the protein possesses any particular distinguishing feature, biologic

activity, or conserved structure. Therefore, the claims are drawn to a genus of polypeptides that are defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

It means little to "invent" a method if one does; not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a cure is illusory, and there is no meaningful possessions of the method. (see 00-CV-6161, March 5th 2003 decision, United States District Court Western District of New York, Judge Larimer).

Therefore, only isolated polypeptides comprising the full length of the amino acid sequence set forth in SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al. (WO 94/05700).

The instant invention is drawn to a detection kit comprising antibodies. Specifically an antibody that recognizes the peptide of SEQ ID NO:1. The antibody recognizes sequences having 80% homology with SEQ ID NO:1 and partial peptides thereof. The antibodies have been prepared by immunizing with virus-like particles, the detection kit can distinguish different serotypes and genotypes. Note for antibodies to recognize a particular sequence requires that a few epitopes be in common, the claims are directed to antibodies the recognize the sequence which does not require the entire sequence.

Matson et al. discloses that individual proteins, particles or proteins aggregates formed from expression of one or more Norwlak virus genes in any prokaryote or eucaryotic expression system are used as an immunogen or inoculate animal to produce polyclonal and monoclonal antibodies for diagnostic assays to detect viral antigens (see pages 34-35, example 9). The comparison of capsid sequences of Norwalk virus and Norwalk-related virus permits the identification of conserved regions of the capsid protein and use of the fragments of such sequences to immunize animals can result in the production of antisera with more broad reactivity to Norwalk related virus (page 35, lines 10-15). Because of sequence conservation the antibodies may detect many other Norwalk related virus. (page 35, lines 27-29). The antibody can be used in ELISA assay to detect viral antigens (page 35, lines 20-23). The reference discloses the use of kits to detect immune response to Norwalk virus (see page 38, example 13; table 4 and claims 103-106). The term "fragment" is used to define any portion of the protein

that can produce an immune response (polyclonal or monoclonal). It is possible that peptides of only 5 amino acids are enough to be immunogenic (see page 11, lines 10-19).

The reference indirectly discloses that the choice of sequences that are unique to a particular sequence will result in antibodies that are specific to the individual virus (see page 35, lines 10-19).

Therefore, the instant invention is anticipated by Matson et al.

Claims 1-4 and 6 rejected under 35 U.S.C. 102(e) as being anticipated by Estes et al. (U.S. Pat. No. 6,572,862 B1).

The instant invention is drawn to a detection kit comprising antibodies. Specifically an antibody that recognizes the peptide of SEQ ID NO:1. The antibody recognizes sequences having 80% homology with SEQ ID NO:1 and partial peptides thereof. The antibodies have been prepared by immunizing with virus-like particles, the detection kit can distinguish different serotypes and genotypes. Note: for antibodies to recognize a particular sequence requires that a few epitopes be in common, the claims are directed to antibodies the recognize the sequence which does not require the entire sequence.

Estes et al. discloses the production of antibodies (see example 6, columns 12-13 and example 9 and table 3) from protein(s) encoded in the cDNA fragments or derivatives thereof, is produced in a prokaryotic or eukaryotic expression system and used to immunize animals to produce polyclonal antibodies for diagnostic assay. Alternatively, synthetic peptides of greater than 15 amino acids made to match the amino acid sequence deduced from the partial cDNA sequence (or from other sequences determined by sequencing additional cDNAs detected with

the original or other clones) are used to immunize animals to produce polyclonal antibodies for diagnostic tests. Reactivities with the expressed protein or synthetic peptides show specificity of the polyclonal sera. Reactivities with other viruses in the Norwalk group (Snow Mountain Agent, Hawaii Agent, Taunton Agent, etc.) indicate production of a reagent which recognizes cross-reacting epitopes. Analysis of the deduced amino acid sequence of the Norwalk virus genome has shown that the Norwalk virus has the genetic organization shown in FIG. 10. Based on this information, one can express the complete genome or subgenomic regions of the genome to produce diagnostic assays to detect viral antigens or immune responses to specific regions of the genome. This information can be used to detect the Norwalk virus, antigens or immune responses to Norwalk virus. This information also can be used to detect other similar currently uncharacterized viruses that cause gastroenteritis or possibly other diseases. Some of these viruses will be in the Caliciviridae or in the picorna virus superfamily. All of these viruses will have matching or similar genomic regions in their DNA sequences.

Therefore, the instant invention is anticipated by Estes et al.

Claims 1-4 and 6 rejected under 35 U.S.C. 102(e) as being anticipated by Estes et al. (U.S. Pat. No. 6,156,833).

The instant invention is drawn to a detection kit comprising antibodies. Specifically an antibody that recognizes the peptide of SEQ ID NO:1. The antibody recognizes sequences having 80% homology with SEQ ID NO:1 and partial peptides thereof. The antibodies have been prepared by immunizing with virus-like particles, the detection kit can distinguish different serotypes and genotypes. Note: for antibodies to recognize a particular sequence requires that a

few epitopes be in common, the claims are directed to antibodies the recognize the sequence which does not require the entire sequence.

Estes et al. discloses the production of antibodies (see claims and example 6) from protein(s) encoded in the cDNA fragments or derivatives thereof, is produced in a prokaryotic or eukaryotic expression system and used to immunize animals to produce polyclonal antibodies for diagnostic assay. Alternatively, synthetic peptides of greater than 15 amino acids made to match the amino acid sequence deduced from the partial cDNA sequence (or from other sequences determined by sequencing additional cDNAs detected with the original or other clones) are used to immunize animals to produce polyclonal antibodies for diagnostic tests. The reference indirectly discloses that the choice of sequences that are unique to a particular sequence will result in antibodies that are specific to the individual virus (see page column 24, lines 19-28).

Therefore, the instant invention is anticipated by Estes et al.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lew et al. (Virology 1994).

The instant invention is drawn to a detection kit comprising antibodies. Specifically an antibody that recognizes the peptide of SEQ ID NO:1. The antibody recognizes sequences having 80% homology with SEQ ID NO:1 and partial peptides thereof. The antibodies have been prepared by immunizing with virus-like particles, the detection kit can distinguish different serotypes and genotypes. Note: for antibodies to recognize a particular sequence requires that a few epitopes be in common, the claims are directed to antibodies the recognize the sequence which does not require the entire sequence. Claim 2 is a product-by process claim for this Office

action, the claim was interpreted as "a composition of matter" (which are *products*). Product by process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113.

Lew et al. discloses using serum, which is a collection of antibodies, from patients that have been infected with virus for the formulation of an immunoprecipitation assay to detect virus in a sample (see figure 3). The reference discloses that there are unique sequences Desert Shield virus and Norwalk virus (see page 324, paragraph 2) allowing for the distinction between the viruses. Therefore, the instant invention is anticipated by Lew et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 6/30/03